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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,862	09/11/2003	Wael R. Joseph	27839-139 (K-C 19,378C)	5051

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No.	Applicant(s)	
	10/659,862	JOSEPH ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-18 and 20-59* is/are pending in the application.

4a) Of the above claim(s) *31-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-18 and 20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' request for continued examination and remarks, which were filed on 28 May 2008.
- Applicants' arguments regarding the U.S. 2004/0228811 reference are persuasive; as such, said reference has been withdrawn as prior art.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 28 May 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-14, 16-18, and 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klofta, *et. al.* (U.S. Patent No. 6,238,682) in view of Krzysik, *et. al.*

(U.S. Patent No. 6,440,437), further in view of Bartels (U.S. Application No. 2003/0157195).

Klofta, *et. al.* teach a tissue product (*see* claim 1). The tissue product is comprised of:

- the emollient (fatty acid) of instant claim 1 (*see* abstract);
- the humectant (polyols) of instant claim 1 (*see* col. 25, line 16);
- the immobilizing agent (fatty alcohols) of instant claim 1 (*see* col. 24, lines 4-14);
- the compatibilizing (propylene glycol) agent of instant claim 1 (*see* col. 17, line 28);
- the fatty acids of instant claim 2 (*see* abstract);
- the dimethicone of instant claim 3 (*see* col. 20, line 18);
- the glycerin of instant claims 5-7 (*see* col. 17, line 21);
- the polyethylene glycol of instant claims 9 and 10 (*see* col. 17, lines 20-42);
- the stearyl alcohol, of instant claim 11 (*see* col. 24, line 11);
- the propylene glycol of instant claim 12 (*see* col. 17, line 22);
- the dispersing agent of instant claim 13 (*see* col. 22, line 24);
- the polydimethylsiloxanes of instant claim 14 (*see* col. 22, line 24); and
- the surfactant of instant claim 25 (*see* col. 5, line 17).

Klofta, *et. al.* explain that combining the disclosed ingredients into one tissue product is beneficial because they impart, "...a soft and lubricious feel..." *See* col. 4, line 41.

Klofta, *et. al.* teach: (1) about 5% to about 50% emollient (*see* col. 19, lines 25 and 26); (2) about 5% to about 60% humectant (*see* col. 17, line 42); (3) about 5% to

about 60% immobilizing agent (*see* col. 27, line 15); and (4) about 5% to about 50% compatibilizing agent (*see* col. 19, lines 25 and 26).

Although Klofta, *et. al.* do not explicitly teach all the percentages recited in instant claims 1, 4, and 8, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

The Klofta, *et. al.* reference is silent with respect to the (1) phase temperatures of instant claims 1 and 28-30; (2) melting point of instant claim 26; (3) and penetration hardness of instant claim 27. Applicants teach concentration ranges of emollient, humectant, immobilizing agent, and compatibilizing agent that overlap with the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been

present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient , a humectant, an immobilizing agent, and a compatibilizing agent into a tissue product, as taught by Klofta, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into a tissue product for the beneficial effect of a soft and lubricious feel, as explained by Klofta, *et. al.*

The Klofta, *et. al.* reference differs from the instant application in that it does not teach the skin barrier of instant claims 15-17, the antioxidant of instant claims 18-20, and the sterol of instant claims 21 and 22.

Krzysik, *et. al.* teach a wipe (*see* abstract) comprising:

- the about 0.1% to about 30% skin barrier enhancing agent of instant claim 1 (*see* col. 4, line 9);
- the oil of instant claim 16 (*see* col. 4, line 2);
- the avocado oil of instant claim 17 (*see* col. 4, line 2);
- 0.3% antioxidant (within the range of instant claim 18; *see* col. 17, Formulas 1-7);
- the about 0.1% to about 10% sterol of instant claim 21 (*see* col. 7, line 56); and
- the cholesterol of instant claim 22 (*see* col. 4, line 4).

Krzysik, *et. al.* explain that combining the disclosed ingredients into one wipe is beneficial because they, "...help maintain skin barrier function..." *See* col. 2, lines 64-65.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, a compatibilizing agent, a skin barrier enhancing agent, an antioxidant, and a sterol into a tissue product, as taught by Klofta, *et. al.* in view of Krzysik, *et. al.*. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into a tissue product for the beneficial effect of a soft and lubricious feel, as explained by Klofta, *et. al.* and to help maintain skin barrier function, as explained by Krzysik, *et. al.*

The Klofta, *et. al.* reference differs from the instant application in that it does not teach the butylated hydroxytoluene of instant claims 1 and 20.

Bartels teaches a diaper composition (*see* abstract) comprising butylated hydoxytoluene (*see* examples 1 and 2).

Bartels explains that the disclosed composition is beneficial in that it can provide relief from the symptoms of diaper rash or skin irritations caused by acidic secretions resulting from teething, antibiotic dosages, bacterial infections or an acidic diet. *See* paragraph 0014.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, a compatibilizing agent, a skin barrier enhancing agent, an antioxidant such as butylated hydroxytoluene, and a sterol into a tissue product, as taught by Klofta, *et. al.* in view of Krzysik, *et. al.*, further in view of Bartels. One of ordinary skill in the art at the time the

invention was made would have been motivated to add butylated hydroxytoluene to a tissue product to prevent skin irritation, as explained by Bartels.

*

2. Claims 1, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klofta, *et. al.* (U.S. Patent No. 6,238,682) in view of Krzysik, *et. al.* (U.S. Patent No. 6,440,437), further in view of Bartels (U.S. Application No. 2003/0157195), further in view of Bowser, *et. al.* (U.S. Patent No. 5,342,976).

Klofta, *et. al.* teach a tissue product (*see* above).

Krzysik, *et. al.* teach a wipe (*see* above).

Bartels teaches a wipe (*see* above).

The Klofta, *et. al.*, Krzysik, *et. al.*, and Bartels references differ from the instant application in that they do not teach the ceramide and glucosylceramide of instant claims 23 and 24.

Bowser, *et. al.* teach a skin composition that may be used in a tissue product, such as a tissue wipe (*see* col. 16, line 44).

The disclosed composition contains the ceramide and glucosylceramide of instant claims 23 and 24 (*see* col. 1, line 67).

Bowser, *et. al.* explain that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." *See* col. 2, lines 7-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a ceramide, such as glucosylceramide to a tissue product, as taught by Klofta, *et. al.* in view of Bowser, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to this ingredient into a tissue product for the beneficial effect of enhancing skin barrier function, as explained by Bowser, *et. al.*

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 16-18, and 20-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969 ('969). Although the conflicting claims are not

identical, they are not patentably distinct from each other because '969 claims an absorbent product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. *See* claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed on 28 May 2008 have been fully considered but they are not persuasive.

1. Applicants argue that the Klofta reference does not disclose a skin barrier enhancing agent or an antioxidant. *See* remarks page 4.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Krzysik was relied upon for the teaching of a skin barrier enhancing agent and Bartels was relied upon for the teaching of an antioxidant, i.e. butylated hydroxytoluene (*see* above).

*

2. Applicants argue that Klofta and Krzysik teach away from each other because Klofta discloses *de minimus* water content (upper limit of 5%) while Krzysik discloses a higher water content (lower limit of 13.5%) *See* remarks, pages 27-29. Applicants make

the same argument for Klofta and Bowser (lower limit of 15%). *See* remarks, pages 10-15.

It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

In this case, Klofta, Krzysik, and Bowser involve the same field of endeavor, i.e. tissue products. Krzysik was relied upon for the teaching of a skin barrier agent, an antioxidant, and a sterol, while Bowser was relied upon for the teaching of a ceramide. Examiner respectfully submits that all four agents would have the same function in the Klofta tissue product as they do in the Krzysik and Bowser tissue products since the functionality of the three agents does not change between a water content of 5% and a water content of 13.5% or 15%.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618